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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/517,723 | 12/10/2004 | Peter Neu | 00143-00245-US | 6056 |

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| EXAMINER | |
|---|---|
| ARNOLD, ERNST V | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1616 | |

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/517,723 | NEU ET AL. | |
| | Examiner | Art Unit | |
| | Ernst V. Arnold | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

The Examiner acknowledges receipt of application number 10/517,723 filed on 12/10/2004. Claims 1-7 are pending and are accordingly presented for examination on the merits.

### *Priority*

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention is directed to non-statutory subject matter. The limitation of instant claim 1 is drawn to xenon gas with an intended use as a medicament for cerebral protection. The Examiner interprets this to read upon xenon gas, which is a natural product.

### *Claim Rejections - 35 U.S.C. §§ 101 and 112, Second Paragraph*

The following are quotations of 35 U.S.C. §§ 101 and 112, second paragraph, respectively, which form the basis of the claim rejections as set forth under this particular section of the Official Action:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 7 are rejected under 35 U.S.C. § 101 as being drawn to use claims, which are non-statutory process claims, as defined in 35 U.S.C. § 101. See, *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967). In addition, claims 6 and 7 are also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More specifically, a claim is rendered indefinite when said claim merely recites a use without any active, positive steps delimiting how this use is actually practiced. See MPEP 2175.03(q). As a result, the Applicants are respectfully required to redraft the aforementioned use claims as statutory process claims that delimit active, positive steps on how to use a composition according to the invention as originally filed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. It is unclear to the Examiner the meaning of "where appropriate". What is appropriate versus inappropriate?

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Fishman (US 5,228,434).

Instant claim 1 is drawn to a medicament for cerebral protection comprising xenon or a xenon-containing gas.

Fishman disclose a mixture consisting of from 60 to 78.5 mole percent stable xenon, from 19.5 to 38 mole percent oxygen and from 2.5 to 20.5 mole percent helium (Claim 1). Methods of making and methods of using the gas mixture are disclosed (Column 3, lines 14-42 and column 5, lines 8-36). The gas mixture is provided to the patient in sufficient amount to anesthetize the patient and thus reads on instant claim 2.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference

between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

***Claim Rejections - 35 USC § 102***

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Petzelt et al. (WO 00/53192).

Petzelt et al. disclose preparations and methods of use of xenon or xenon gas mixtures for treating neurointoxications (a chronic cerebral disorder such as Parkinson's disease) in a therapeutically useful concentration (Page 5, paragraph 1; page 11, paragraph 4 and claims 1, 7 and 16, for example). The preparation can have a ratio of xenon to oxygen of 80 to 20 percent by volume thus reading on instant claims 1-3 (Page 8, second paragraph and claims 15 and 17). Administration is by simple inhalation (Page 12, line 1). Methods of mixing the gases are provided (Page 8, paragraphs 3 and 4). Methods of administration are also provided (Page 9, paragraphs 1 and 2).

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the

intended use does not create a structural difference, thus the intended use is not limiting.

***Claim Rejections - 35 USC § 102***

Claims 1 and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Briend et al. (WO 97/15311).

Briend et al. disclose nitrogen monoxide (NO) composition for use as a drug (Title). The use of a gaseous composition containing NO and carbon dioxide for preparing a drug useful for the intravascular treatment or prevention of ischaemia is disclosed (Abstract and claim 1). The gaseous drug additionally comprises at least one gas chosen from the group of nitrogen protoxide, xenon, krypton and their mixtures (Claims 1 and 3). Briend et al. thus disclose the instantly claimed composition comprising xenon and NO.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

***Claim Rejections - 35 USC § 102***

Claims 1 and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Briend et al. (US 5,670,177).

Biend et al. disclose a gaseous mixture for treatment of prevention of ischemia comprising: nitric oxide in an amount effective to prevent ischemia; carbon dioxide; nitrogen protoxide; and at least one of xenon, krypton, and their mixtures (Claims 1 and 2). Briend et al. thus disclose the instantly claimed composition comprising xenon and NO.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

***Double Patenting***

1) Claims 1-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 8-12 of copending Application No. 10/518,067. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims embrace or

are embraced by the copending claims. Instant claim 1 and copending claim 1 recite the same composition. The Examiner interprets NO to be a hemogenous medicament because it is transported by the blood stream and thus instant claim 4 makes obvious instant copending claim 2. Instant claims 1 and 2 make obvious gaseous xenon present in a therapeutically effective amount of copending claims 3, 5, 10 and 12. The gaseous preparation of instant claim 4 makes obvious inhalation of copending claims 4 and 11. Instant claim 4 also makes obvious simultaneous, separate or sequential use of copending claim 6. Instant claim 6 recites production of a medicament to treatment of brain disorders, which makes obvious copending claim 8. Instant claim 7 is drawn to the use of a xenon gas mixture for cerebral protection, which makes obvious copending claim 9.

One of ordinary skill in the art would have recognized the obvious variation of the instant claims in the copending application because of the overlap in claimed subject matter as stated above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2) Claims 1-2 and 4-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6, 7 and 9 of copending Application No. 10/10/517,722. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims embrace or are embraced by the copending claims. Instant claim 1 and copending claim 1 are drawn to xenon or xenon-containing gas mixtures. Instant claim 2 and copending

claim 2 are drawn to therapeutically effective amounts of xenon. Instant claim 4 comprises an NO source and xenon which makes obvious copending claims 4 and 6 composition comprising xenon and a spasmolytic. NO is a spasmolytic. Instant claim 5 and copending claims 2 and 3 are drawn to therapeutically effective amounts of NO and xenon. Instant claim 6 and copending claim 7 are drawn to the use of the xenon and where appropriate NO source. Instant claim 7 and copending claim 9 are drawn to the use of xenon and where appropriate an NO source for the therapy or prophylaxis of impairments of cognitive performance.

One of ordinary skill in the art would have recognized the obvious variation of the instant claims in the copending application because of the overlap in claimed subject matter as stated above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3) Claims 1 and 3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 24, 25, 28 and 29 of copending Application No. 10/380,869. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims embrace or are embraced by the copending claims. Instant claim 1 is drawn to a medicament comprising xenon or a xenon-containing gas mixture. Instant claim 3 is drawn to the medicament of instant claim 1 further comprising as remainder oxygen or oxygen and an inert gas. Copending claim 22 is drawn to a drug comprising xenon. Copending claims 24 and 28 are drawn to a xenon in a gas mixture and copending

claim 25 is drawn to pure xenon. Copending claim 29 is drawn to the remainder of the gas mixture comprising oxygen or oxygen and an inert gas.

One of ordinary skill in the art would have recognized the obvious variation of the instant claims in the copending application because of the overlap in claimed subject matter as stated above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EVA

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